AUG 1 0 2000 K002190

Cp Medical

836 NE 24TH Ave Portland, OR. 97232
PO Box 6724 Portland, OR. 97208
TEL.(503) 232-1555 Fax (503)230-9993
E-Mail cpmedical@aol.com

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of Safe Medical Devices Act of 1990. 21 CFR 807.92

Device Name:

Trade Name: *Polyglycolic Acid (PGA)*

Common Name(s): Absorbable suture, synthetic absorbable suture, PGA suture

Classification Name(s): Suture, Absorbable, Synthetic, Polyglycolic Acid

Establishment Name, Contact & Registration Number:

Name: C.P. Medical
836 N.E. 24th. Ave
Portland, Oregon 97232
Tele: (503) 232-1555
Fax: (503) 230-9993
FDA REG.No. 3032563

Contact: Patrick Ferguson, (President)
or
Thomas Brammer (V.P. Manufacturing)

Classification:

Device Class: Class ll

Classification Panel: General & Plastic Surgery

Product Code: 79GAM

Intended Use:

Polyglycolic Acid (PGA) Absorbable Surgical Sutures are indicated for use in general soft tissue approximations; including Ophthalmic surgery, but not for use in Cardiovascular and Neurological tissue approximation.

Equivalent Predicated Device:

C.P. Medical believes that the Polyglycolic Acid (PGA) Absorbable Suture is substantially equivalent to the following absorbable suture marketed by Sherwood Davis & Geck:

> Dexon® ll polyglycolic acid, synthetic absorbable surgical sutures with polycaprolate coating system.

With respect to substantial equivalence, the comparison device represents a virtually identical device. Materials, packaging, sterilization methods, sizes multi- and monofilament, dyed and undyed as well as functional characteristics (absorption rate, strength, etc.) Equivalency can also be drawn with respect to the design, material composition, performance and intended use. Polyglycolic Acid (PGA) and Dexon® ll both meet or exceed the performance requirements set forth by USP 24.

Patrick J. Ferguson, President

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 0 2000

Mr. Patrick Ferguson
President
CP Medical
836 NE 24th Avenue
Portland, Oregon 97232

Re: K002190
Trade Name: Polyglycolic Acid (PGA) Synthetic Absorbable Suture
Regulatory Class: II
Product Code: GAM
Dated: July 6, 2000
Received: July 20, 2000

Dear Mr. Ferguson:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices that were regulated as transitional devices and that have been reclassified into class II. Notice of this reclassification was published in the Federal Register on Wednesday, September 18, 1991 (Vol. 56, No. 18, Pages 47150 and 47151). A copy of this Federal Register can be obtained by calling the Division of Small Manufacturers Assistance (DSMA) at (800) 638-2041 or (301) 443-6597. You may, therefore, market the device subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act) and the following limitations:

1. The Polyglycolic Acid (PGA) Synthetic Absorbable Surgical Suture is indicated for use in general soft tissue approximation and/or ligation, including use in ophthalmic procedures, but not for use in cardiovascular and neurological procedures.

2. This device may not be manufactured from any material other than homopolymers and copolymers made from glycolide and/or L-lactide. Any deviation of the polymer composition or processing as described in this 510(k) notification must be submitted to FDA in a new premarket notification at least 90 days prior to implementation of the proposed change(s). In addition, you must maintain documentation at your premises regarding vendor certification for raw or semiprocessed source material, all manufacturing and quality control release procedures, and validation of sterilization procedures used in the manufacturing of the Polyglycolic Acid (PGA) Synthetic Absorbable Surgical Suture. Any deviation of the source material or processing as described in this 510(k) notification requires submission of a new premarket notification and Food and Drug Administration (FDA) clearance prior to commercial distribution of the modified device.

The sale, distribution and use of this device are restricted to prescription use in accordance with 21 CFR 801.109.

The general controls provisions of the Act include requirements for registration, listing of devices, good manufacturing practice, and labeling, and prohibition against misbranding and adulteration.

Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Diane R. Lochner

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K002190

Device Name(s): ***Polyglycolic Acid (PGA)***

Intended Use(s) of the Device:

General soft tissue approximation; including use in Ophthalmic surgery, but not for use in Cardiovascular and Neurological tissue approximation.

Please do not write below this line - continue on another page if necessary

Concurrence of CDRH, Office of Device Evaluation (ODE)

Dunne R. Vochniak

ision Sign-Off)

ion of General Restorative Devices

Number K002190

Prescription Use ✓ or Over-The-Counter Use _____

(per 21 CFR 801.109) (Optional format 1-2-96)